

## **Amendment in the Nature-of-a-Substitute to HR. 2768: Medicare Regulatory and Contracting Reform Act of 2001**

### **Section 1. Short Title; Amendments to Social Security Act; Table of Contents**

*Current Law.* No provision.

*Explanation of Provision.* Except as otherwise specified, the provisions would amend or repeal a section or other provisions of the Social Security Act. None of the provisions shall be construed to (1) compromise the existing legal authority for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent the Department of Health and Human Services (HHS) from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare’s administrative contracting (as provided for in this bill) would not consolidate the Federal Hospital Insurance Trust Fund which pays for Part A services and the Federal Supplementary Medical Insurance Trust fund which pays for Part B services. The bill notes that this administrative consolidation does not reflect any position on that issue. Finally, the term, “supplier,” means a physician, practitioner, facility, or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated..

*Effective Date.* Upon enactment.

### **Section 2. Issuance of Regulations**

#### **(a) Consolidation of Promulgation to Once a Month.**

*Current Law.* The Secretary is required to prescribe regulations that are necessary to administer Parts A and B of the Medicare program. No rule, requirement or policy statement (other than a national coverage determination) that establishes or changes a substantive legal standard that determines Medicare’s scope of benefits, level of payment, or eligibility of individuals, entities or organizations to receive benefits or furnish services can take effect unless it is promulgated by regulation. The Secretary must publish a proposed regulation in the *Federal Register*, with at least 60 days to

solicit public comment, before issuing the final regulation with the following exceptions: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementation of a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of Title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest.

*Explanation of Provision.* The Secretary would be required (1) to issue proposed or final regulation (including interim final regulation) only on one business day of the month unless publication on another date is necessary to comply with statutory requirements and (2) coordinate the issuance of new regulations relating to a category of provider or supplier based on an analysis of the collective impact of the regulatory changes on such category. No later than 3 years after enactment, the Secretary would be required to report to Congress on the feasibility of issuing regulations only on one day in each calendar quarter.

*Effective Date.* The provisions would apply to regulations issued 30 days after enactment.

#### **(b) Regular Timeline for Publication of Final Rules.**

*Current Law.* See above. The Secretary must publish in the *Federal Register* no less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

*Explanation of Provision.* The Secretary, in consultation with the Director of the Office of Management and Budget, would establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The timeline may vary by regulation due to complexity, number and scope of comments received and other factors. The Secretary would be required to publish in the Federal Register any variations in the timeline for publication of the final regulation. This notice of the different timeline would need to: (1) be published no later than the end of the comment period for the proposed regulation and (2) include a brief explanation of the justification for such variation. If the regular timeline established for an interim final regulation expires without

promulgation of a final regulation (and associated public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that would include an explanation for not complying with the regular timeline. The interim regulation's regular timeline would be restarted on the date that the notice of continuation is published. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable timeline.

*Effective Date.* Upon enactment. The Secretary would be required to provide for a transition period for previously published interim final regulations.

**(c) Limitation on New Matter in Final Regulations.**

*Current Law.* No provision.

*Explanation of Provision.* A provision in a final regulation that is not a logical outgrowth of the proposed regulation would be treated as a proposed regulation and would not take effect without a separate public comment period followed by publication as a final regulation.

*Effective Date.* Upon enactment.

**Section 3. Compliance with Changes in Regulations and Policies**

**(a) No Retroactive Application of Substantive Changes; Timeline for Compliance with Substantive Changes after Notice.**

*Current Law.* No provision.

*Explanation of Provision.* A substantive change in Medicare regulations, manual instructions, interpretive rules, policy statements, or guidelines would not be applied retroactively to items or services furnished before the date it was issued, unless the Secretary determines that retroactive application would be necessary to comply with statutory requirements or would have a positive impact on beneficiaries or providers and suppliers. The substantive change would not be effective until at least 30 days after it is issued. No compliance action could be taken against a provider or supplier

with respect to the change for items and services furnished before the effective date.

*Effective Date.* Upon enactment.

**(b) Reliance on Guidance**

*Current Law.* No provision.

*Explanation of Provision.* If (1) a provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor and (3) the guidance is inaccurate, the provider or supplier would not be subject to any sanction including repayment or any penalty. This provision would not be construed to require repayment (or payment of penalties) to the extent that the overpayments result from a clerical or technical error.

*Effective Date.* Upon enactment.

**Section 4. Increased Flexibility in Medicare Administration**

**(a) Consolidation and Flexibility in Medicare Administration.**

*Current Law.* Section 1816 of the Social Security Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts with health insurers carriers to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. Section 1893 authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal

intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

*Explanation of Provision.* The legislation would add Section 1874A to the Social Security Act which would permit the Secretary to enter into contracts with any entity to serve as a Medicare administrative contractors. These contractors would perform or secure the performance (through subcontracting) some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; assist, consult and communicate with providers and suppliers; and perform additional functions as necessary. The claims processing jurisdiction of Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would

perform a particular function or activity is the entity that has the contract for that activity for any given beneficiary, any given provider or supplier, or class of provider or supplier.

The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract but would be able to renew a contract for up to 5 years without regard to statutory requirements concerning competitive contracting if the entity has exceeded specified performance standards. These standards would take into account performance quality as well as price and other factors. Functions would be able to be transferred among Medicare administrative contractors as consistent with these provisions. The Secretary would be required to (1) consider performance quality in such transfers; (2) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (3) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. With respect to developing the performance standards, the Secretary would be able to consult with providers, suppliers and organizations performing the contracting functions. The Secretary would be required to contract only with those entities that (1) will perform efficiently and effectively; (2) will meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) will agree to furnish timely and necessary data; and (4) will maintain and provide access to necessary records and data.

A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of the identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of DME. An entity with a MIP contract would not be treated as a Medicare administrative contractor, solely by reason of the MIP contract. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the inclusion of the existing standards in effect for timeliness of reviews, fair hearings, reconsiderations and exemption decisions.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to provide a surety bond to the United States in an amount established by the Secretary. The liability standard of “gross negligence” is retained but the agency and organization is now liable under “gross negligence and intent to defraud”: neither the contractor nor the contractor’s employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor’s employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon an authorization from the certifying employee AND the authorization meets the internal control standards established by General Accounting Office (GAO). The Secretary would pay the Medicare administrative contractor, its employees, or their legal representatives for defending these contractors or employers in a civil action related to the performance of their contractual duties, if due care was exercised in the performance of such duties. These payments would be equal to the reasonable amount of legal expense incurred.

*Effective Date.* See subsection (d).

**(b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries).**

*Current Law.* Section 1816 of the Social Security Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

*Explanation of Provision.* The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor’s overpayment recovery efforts would be retained.

*Effective Date.* See subsection (d).

**(c) Conforming Amendments to Section 1842 (Relating to Carriers).**

*Current Law.* Section 1842 of the Social Security Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

*Explanation of Provision.* The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). Certain instructions including those pertaining to nursing facilities' payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. Carrier fair hearing requirements would be eliminated. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

*Effective Date.* See subsection (d).

**(d) Effective Date; Transition Rule.**

*Current Law.* No provision.

*Explanation of Provision.* Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2003. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis to transition from the contracts established under sections 1816 and 1842 of the Social Security Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2008. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. The MIP contracting exception that allows agreements according to current law would be deemed to be a contract established under the new authority of 1874A and would continue existing activities.



## **(e) References**

*Current Law.* No provision.

*Explanation of Provision.* After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

## **Section 5. Provider Education and Technical Assistance.**

### **(a) Coordination of Education Funding.**

*Current Law.* Medicare's provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

*Explanation of Provision.* The provision would add Section 1889 to the Social Security Act which would require the Secretary to (1) coordinate the educational activities provided through the Medicare administrative and MIP contractors and (2) to submit an evaluation to Congress on actions taken to coordinate the funding of provider education.

*Effective Date.* Upon enactment with report due to Congress no later than October 1, 2002.

### **(b) Incentives to Improve Contractor Performance.**

*Current Law.* No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error

rates.

*Explanation of Provision.* The Secretary would be required to (1) develop a methodology, in consultation with representatives of providers and suppliers, to measure the specific claims payment error rates at each Medicare administrative contractor; and (2) identify best practices developed at each contractor for educating providers and suppliers. The Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs and (2) whether methodology should be used as the basis of bonuses for contractors. The report shall also include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

*Effective Date.* Methodology is to be implemented and report is due to Congress by October 1, 2003.

**(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.**

*Current Law.* No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

*Explanation of Provision.* Each Medicare administrative contractor would be required to (1) respond clearly, concisely and accurately to billing and cost reporting questions; (2) maintain a toll-free telephone number for such inquiries; (3) maintain a system for identifying, and disclosing on request, which employee provided the information; and (4) monitor the quality of the information provided. The Secretary would be required, in consultation with provider organizations, to establish performance standards with respect to telephone inquiries from providers and suppliers.

*Effective Date.* October 1, 2003.

**(d) Improved Provider Education and Training.**

*Current Law.* In FY2000, \$54.8 million was spent on provider education and training activities: about \$43 million from the program management appropriation and about \$12 million came from the Provider Education and Training component of MIP. In FY2001, about \$57.3 million was budgeted for these activities.

*Explanation of Provision.* The provision would authorize an increased \$10 million appropriation from Medicare trust funds (as appropriate from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) in FY2003 and FY2004 to increase Medicare contractors' billing, coding and other provider training activities. Medicare administrative contractors would be required to conduct education and training activities for small providers of services or suppliers, that is, institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs.

*Effective Date.* October 1, 2002.

**(e) Requirement to Maintain Internet Sites.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary and each Medicare administrative contractor would be required to maintain an Internet site which provides easily accessible answers to frequently asked questions as well as other published materials of the contractor.

*Effective Date.* October 1, 2002.

**(f) Additional Provider Education Provisions.**

*Current Law.* No provision.

*Explanation of Provision.* A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track providers or suppliers for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors

to disclose claims processing screens (computer edits that trigger medical review) or information that would compromise pending law enforcement activities or law enforcement-related audits.

*Effective Date.* Upon enactment.

#### **Section 6. Small Provider Technical Assistance Demonstration Program.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would be required to establish a demonstration program which offers technical assistance, when requested, to small providers or suppliers, that is, institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs. Technical assistance would include direct, in-person examination of billing systems and internal controls by qualified entities such as peer review organizations or other entities. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the Office of the Inspector General (OIG) in HHS or the GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25% of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than 2 years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The evaluation would also study whether improper payments were made as a result of the demonstration. The provision would authorize \$1 million in FY2003 and \$6 million in FY2004 of appropriations from the Medicare Trust Funds to carry out demonstration project.

*Effective Date.* Upon enactment.

#### **Section 7. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.**

*Current Law.* No statutory provisions address Medicare Provider or Beneficiary Ombudsman programs. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

*Explanation of Provision.* The Secretary would be required to appoint a Medicare Provider Ombudsman to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program including peer review and administrative requirements; and (2) recommend changes to improve program administration.

The Secretary would be required to appoint a Medicare Beneficiary Ombudsman from individuals with health care expertise and advocacy. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration.

The provision would authorize appropriations of necessary sums in FY2002 and subsequently from the appropriate Medicare Trust Funds for the these Ombudsman programs.

The Secretary would be required to establish a toll-free number (1-800-MEDICARE) which will transfer individuals with questions or seeking help to the appropriate entities. The transfer would occur with no charge. This toll-free number would be the general information and assistance number listed on the annual notice provided to beneficiaries.

*Effective Date.* Upon enactment.

## **Section 8. Provider Appeals.**

### **(a) Medicare Administrative Law Judges.**

*Current Law.* Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services, may appeal claims that are denied or payments that are reduced. Section 1869 of the Social Security Act was amended by Benefits Improvement and Protection Act of 2000 (BIPA) in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that decision through a series of administrative appeals and then into federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an administrative law judge (ALJ) in the Social Security Administration (SSA) is one component of the administrative appeals process.

*Explanation of Provision.* By October 1, 2003, the Commissioner of SSA and the Secretary would be required to develop and implement a plan to transfer ALJs responsible for hearing Medicare cases from SSA to Health and Human Services. This plan would include recommendations on the number of judges and support staff required to adjudicate cases on a timely basis and funding needed for FY2004 and subsequently. The provision would authorize increased appropriations, in addition to amounts otherwise appropriated, from the appropriate Medicare Trust fund of \$5 million in FY2003 and as necessary subsequently in order to increase the number of administrative law judges and to improve education and training programs for judges and their staff in carrying out their Medicare activities. Nothing in this provision would be construed to affect the independence of ALJs in carrying out their responsibilities for adjudicating cases.

*Effective Date.* Upon enactment with the mandated report concerning ALJ transfer due by October 1, 2003.

### **(b) Process for Expedited Access to Judicial Review.**

*Current Law.* Section 1869 (as modified by BIPA but not yet implemented) provides for expedited proceedings. Under BIPA provisions, an expedited determination is available to a beneficiary who has received notice: (1) that a provider plans to terminate services and a physician certifies that failure to continue services is likely to place the beneficiary's health at risk; or (2) the provider plans to discharge the beneficiary. In instances where the moving party alleges that no material issues of fact

are in dispute, the Secretary will make an expedited determination as to whether any such facts are in dispute and, if not, will render a decision expeditiously.

*Explanation of Provision.* The Secretary would be required to establish a process where a provider or supplier of a service or a beneficiary who has filed an appeal may obtain access to judicial review when a *review panel* determines, no later than 60 days after the date of the written request and submission of supporting documentation, that it does not have the authority over law or regulation in question and where material facts are not in dispute. If so decided, the appellant would be able to bring a civil court action if the civil action is filed within 60 days. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court in DC. The amount in controversy would be subject to annual interest awarded to the prevailing party by the reviewing court. The provision for expedited access to judicial review would apply to a provider's appeal concerning program participation.

A review panel would be an administrative law judge (ALJ), the Departmental Appeals Board (DAB), a Qualified Independent Contractor (QIC) or other designated entity. A decision by the review panel would be a final decision and would not be subject to review by the Secretary. The appellant would be able to request this determination only once with respect to a particular question of law or regulation.

These expedited access to judicial review provisions will also apply to application of termination proceedings, relating to survey and certification determinations, under 1866(h).

*Effective Date.* Applies to appeals filed on or after October 1, 2002.

### **(c) Requiring Full and Early Presentation of Evidence.**

*Current Law.* No provision.

*Explanation of Provision.* A provider of services or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

*Effective Date.* On or before October 1, 2002.

## **Section 9. Recovery of Overpayments and Prepayment Review; Enrollment of Providers.**

### **(a) Recovery of Overpayments and Prepayment Review.**

*Current Law.* No specific statutory provisions address the payment plans, consent settlements, prepayment, or postpayment actions. Section 1833(j) of the Social Security Act provides that interest accrues on underpayments or overpayments starting 30 days of the date of the final determination of the accurate payment amount.

*Explanation of Provision.* Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers would be allowed to repay overpayment amounts over a period of up to 3 years when their overpayment obligation exceeds a 10% threshold of their annual payments from Medicare. The Secretary would be able to determine cases of extreme hardship where a repayment period of up to 5 years could be established. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish the way that newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plans would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where bankruptcy may be declared or fraud or abuse is suspected.

For providers and suppliers who appeal an overpayment determination, the Secretary would be prevented from recovering an overpayment until the date of the ALJ decision. The Secretary would be required (1) to collect interest which accrues starting on the date of the overpayment notice if the appeal decision is against the provider, physician, practitioner or supplier and (2) to pay the recouped amount plus interest if the appeal decision is subsequently reversed.

Medicare contractors, both MIP and Medicare administrative contractors, would be able to conduct random prepayment reviews only in order to develop contractor-wide or program-wide claims payment error rates. These random prepayment reviews would be developed in consultation with providers and suppliers. Contractors would be able to deny payments for claims subject to the prepayment reviews.



Medicare contractors would not be able to use extrapolation to determine overpayment amounts unless a sustained or high level of payment error exists (as defined by the Secretary through regulations) or a documented educational intervention did not correct the payment error.

Medicare contractors would be permitted to periodically request records or documentation for a limited sample of claims from providers or suppliers who had been overpaid to ensure that the previous practices have been corrected.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. As part of the process, the Secretary would be required to (1) communicate in a non-threatening manner to a provider, or supplier that based on a preliminary analysis of medical records an overpayment may exist; (2) provide 45-days where additional information may be submitted by the provider and supplier on these medical records; (3) after considering the additional information, provide notice and explanation of any remaining overpayment determination; and (4) offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Medicare contractors would not be able to implement (non-random) prepayment review based on initial identification of an improper billing practice by the provider or supplier unless a sustained or high level of payment error exists. The Secretary would be required to issue regulations concerning the timing and termination of prepayment reviews as well as the different circumstances that would affect the duration of these reviews.

Medicare contractors would be required to provide a written notice of the intent to conduct a post-payment audit to providers, and suppliers selected as audit candidates. During the exit conference between the provider or supplier and the contractor, the contractor would be required to provide a full review and understandable explanation of the findings to those who have been audited. This full review (1) would permit the development of an appropriate corrective action plan; (2) would provide information on appeal rights; (3) would provide for an opportunity to supply additional information to the contractor; and (4) take into account that additional information which was provided on a timely basis. A notice of audit or explanation of findings would not be not required if law enforcement activities or audits would be

compromised.

The Secretary would be required to establish a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

*Effective Date.* Upon enactment.

**(b) Enrollment Process for Providers of Services and Suppliers.**

*Current Law.* Providers and, to some extent suppliers, have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Social Security Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to suppliers. Sections 1128(a) and (b) of the Act provide for the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f) provides for hearing and judicial review for exclusions. In 1999, the Health Care Financing Administration (HCFA—now the Centers for Medicare and Medicaid Services or CMS) published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

*Explanation of Provision.* The Secretary would be required to establish by regulation an enrollment process which provides an appeal mechanism with prompt deadlines for those providers and suppliers whose applications to participate in Medicare are denied.

*Effective Date.* Within 6 months of enactment.

**(c) Process for Correction of Minor Errors and Omissions on Claims Without Pursuing Appeals Process.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would be required to develop, in

consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors can be corrected and resubmitted without appealing the claims denial.

*Effective Date.* Upon enactment.

#### **Section 10. Beneficiary Outreach Demonstration Program.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would be required to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of the offices would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) recommend whether the demonstration should be established on a permanent basis.

*Effective Date.* Upon enactment.

#### **Section 11. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would not be permitted to implement any documentation guidelines for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded by appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce

paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to (1) enhance clinically relevant documentation; (2) decrease the non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be (1) conducted in consultation with practicing physicians; (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established, including a peer review method by physicians as well as projects in a rural area, outside rural areas as well as in a teaching setting and nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. The Secretary, in consultation with practicing physicians, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress.

*Effective Date.* Upon enactment.

## **Section 12. Improvement in Oversight of Technology and Coverage.**

### **(a) Improved Coordination Between FDA and CMS on Coverage of Breakthrough Medical Devices.**

*Current Law.* No provision.

*Explanation of Provision.* To the extent feasible, the Secretary would be required to coordinate and share appropriate information under reviews of Medicare

coverage decisions and Federal Drug Administration's (FDA) reviews of applications for premarket approval of class III medical devices under Section 515 of the Federal Food, Drug, and Cosmetic Act. The Secretary would be required to submit an report on the implementation plan to lessen the delay between FDA's premarket approval and Medicare's coding and coverage decisions to the appropriate Congressional committees. This provision would not change Medicare's coverage nor FDA's premarket approval criteria.

*Effective Date.* Upon enactment with report to Congress on implementation plan due no later than 6 months after enactment.

**(b) Council for Technology and Innovation.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary is required to establish a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS). The council would be composed of senior CMS staff with a coordinator who reports to the CMS administrator. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

*Effective Date.* Upon enactment.

**(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.**

*Current Law.* No provision.

*Explanation of Provision.* GAO would be required to conduct a study which analyzes how external data can be collected for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

*Effective Date.* Report is due no later than October 1, 2002.

**(d) Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals.**

*Current Law.* No provision.

*Explanation of Provision.* Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

*Effective Date.* Applies to hospitals as of July 1, 2002.

**(e) IOM Study on Local Coverage Determinations.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would be required to arrange for a study by the Institute of Medicine (IOM) that would examine the capabilities and information available to establish Medicare's local coverage determinations. The study would examine: (1) the consistency of definitions used in the determinations; (2) the extent to which the determinations are based on evidence; (3) whether, in the absence of adequate data, determinations to cover experimental items or services are made in order to collect data.

*Effective Date.* The IOM study would be due to the Secretary no later than 3 years after enactment when it would be promptly transmitted to Congress..

**(f) Assignment of HCFA Common Procedural Coding System (HCPCS) Level II Coding.**

*Current Law.* No provision.

*Explanation of Provision.* The Secretary would not be able to require more than 3 months of marketing experience as a condition for the assignment of technology-specific HCPCS Level II codes except in cases that the Secretary deems the new technology to be insignificant.

*Effective Date.* Upon enactment.

### **Section 13. Miscellaneous Provisions.**

#### **(a) Treatment of Hospitals for Certain Services Under the Medicare Secondary Payor (MSP) Provisions.**

*Current Law.* In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor is the Medicare program's process for coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

*Explanation of Provision.* The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

*Effective Date.* Upon enactment.

#### **(b) Clarification of Prudent Layperson Test for Emergency Services Under the Medicare Fee-for-Service Program.**

*Current Law.* Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exist prior to

asking about insurance status of the patient.

*Explanation of Provision.* Services that are provided by a hospital or a critical access hospital to Medicare beneficiary who is not enrolled in Medicare +Choice plans in order to evaluate or stabilize an emergency medical condition that meet the application of the prudent layperson rule are deemed to be reasonable and necessary covered services.

*Effective Date.* Effective for items or services furnished on or after January 1, 2002.